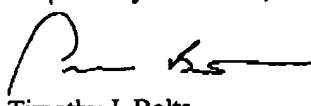
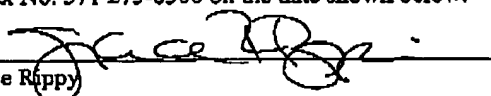


|  |                      |                             |
|--|----------------------|-----------------------------|
| <b>PRE-APPEAL BRIEF REQUEST FOR REVIEW</b><br>(filed with the Notice of Appeal)  |                      | Docket Number 035576/233803 |
| Application Number 09/842,466  | Filed April 26, 2001 |                             |
| First Named Inventor Hiroyasu Kokubo   |                      |                             |
| Art Unit 1616  | Examiner H.N. Sheikh |                             |
| <p>Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.</p> <p>This request is being filed with a notice of appeal.</p> <p>The review is requested for the reason(s) stated on the attached sheet(s).<br/>Note: No more than five (5) pages may be provided.</p> <p>Respectfully submitted,</p> <p><br/>Timothy J. Balts<br/>Registration No. 51,429</p> <p>Date <u>January 4, 2006</u></p> <p><b>Customer No. 00826</b><br/><b>ALSTON &amp; BIRD LLP</b><br/>Bank of America Plaza<br/>101 South Tryon Street, Suite 4000<br/>Charlotte, NC 28280-4000<br/>Tel Charlotte Office (704) 444-1000<br/>Fax Charlotte Office (704) 444-1111</p> |                      |                             |
| <p style="text-align: center;"><b>CERTIFICATION OF FACSIMILE TRANSMISSION</b></p> <p>I hereby certify that this paper is being facsimile transmitted to the US Patent and Trademark Office at Fax No. 571 273-8300 on the date shown below.</p> <p><br/>Grace Rippy</p> <p><u>January 4, 2006</u><br/>Date</p>  |                      |                             |

Appln. No.: 09/842,466  
Reply to Office Action of 07/28/2005

Attachment  
Reasons for Requesting Pre-Appeal Brief Request For Review

**I. Independent Claims 31 and 33 are patentable over U.S. Patent No. 5,089,270 to Hampton et al.**

The invention defined in independent Claims 31 and 33 is directed to a solid preparation having a continuous multi-colored coating layer. The continuous multi-colored coating is provided by coating a solid preparation with a continuous coating layer having one or more colorants. Portions of the coating layer are then exposed to radiation, such as light, in an amount that is sufficient to cause a change in color in the colorants that are exposed to the radiation. In some of the claimed embodiments, the above-described process can be used to form solid preparations that are coated with a continuous coating layer having complex images such as logos and bar-codes.

Claims 31 and 33 have been rejected under 35. U.S.C. § 103(a) as being unpatentable over Hampton. Hampton describes a multi-colored tablet that is coated with a clear coating. The multi-coloration is achieved by combining a first powder material containing a first coloring agent with a second powder material containing a second coloring agent. The two powders are compressed to form a solid tablet having a demarcation line between the first material and the second material. See column 4, line 3 to column 5, line 20. The two-colored tablet is subsequently coated with a clear gelatin layer through which the color components are visible. See column 5, lines 37-49. The gelatin layer is clear and is not multi-colored. The two color sections comprise the core of the tablet and are not part of the coating.

In order to establish a *prima facie* case of obviousness, three basic criteria must be met: 1) the reference(s) must teach or suggest all the claim limitations 2) there must be some suggestion to modify the references; and 3) there must be some reasonable expectation of success. The Office has failed to establish a *prima facie* case of obviousness because the Examiner has failed to establish any of the above criteria. Therefore the rejection should be withdrawn.

First, Hampton fails to disclose or suggest each and every limitation of Claims 31 and 33. In particular, the claims recite a solid preparation having a structure that includes a "multi-colored continuous film coating layer." The claims further recite that the "different coloration" in the coating layer is produced by exposing portions of the coating layer to radiation. As a

Appln. No.: 09/842,466

Reply to Office Action of 07/28/2005

result, the solid preparation has a continuous coating layer wherein the different colorations are disposed in the coating layer itself. This structure is not disclosed or suggested by Hampton. In contrast, Hampton describes a tablet wherein the colored components are not in the coating layer at all, but rather comprise two distinct portions in the interior of the tablet that are compressed together. In the Office Action of July 7, 2005, the Examiner alleges that Hampton anticipates the claimed invention because the “prior art recognizes and teaches a tablet that is multi-colored and has two layers that provide for distinct colors with different color sections.” (Emphasis added). However, as pointed out above, the claimed invention recites a structure wherein the different colorations are in a continuous coating layer. The different colorations are not in two layers or in two separate components in the core of the tablet. Thus, Hampton fails to teach the claimed invention because it does not disclose a solid preparation having a continuous multi-colored film coating layer.

Further, there is no teaching or suggestion in Hampton of how to prepare a continuous coating having different colorations. According to Hampton, the coloring agents are contained in the first and second powders used to make the body of the tablet rather than in a coating layer. In fact, Hampton’s specific description of a clear coating layer teaches away from the recited different colorations in the multi-colored coating layer. In contrast, the claimed invention recites that parts of the solid preparation are exposed to radiation that results in a different coloration in the part of the coating that is exposed to the radiation. As a result, the solid preparation of the claimed invention is different than the tablet of Hampton.

Second, in order to modify a reference, there must be some suggestion to do so. In the Office Action of July 7, 2005, the Examiner stated that “[t]he prior art recognizes and teaches a tablet that is multi-colored and has two layers that provide for distinct colors with different color sections, provided for easy recognition of the tablet. The prior art formulations provide for tablets having multi-colored arrangements, albeit in the body of the tablet.” See page 5 (emphasis added). From this excerpt, it can be gleaned that the Examiner is attempting to assert that since Hampton teaches the use of two powders of different coloring in the interior of the tablet, it would therefore be obvious to modify the clear coating of Hampton to include two different colorants. However, there is no disclosure or suggestion in the prior art to provide any motivation to modify Hampton’s clear coating layer and to provide differences in coloration in the coating layer. Hampton clearly teaches that the differences in coloration arise from the core,

Appln. No.: 09/842,466

Reply to Office Action of 07/28/2005

not the outer coating. For example, Hampton teaches that the tablet includes two distinct color sections 14, 18 that form "halves of tablet core 12." See column 3, lines 10-19 (emphasis added). Further, Hampton teaches that this colored core is coated with a clear material. See column 3, lines 15-16 and column 5, lines 37-49. There is no suggestion in Hampton to include different colorations in the coating. The only possible suggestion to do so comes from Applicants' own disclosure, which is impermissible.

In addition to lacking the necessary suggestion to modify the coating, there is also no teaching in Hampton of how to modify the coloration of the outer coating. In the absence of a disclosure in Hampton as to how such a modification could be achieved in the outer coating, the person of ordinary skill in the art would have no motivation or reason to make a modification to the outer coating. The only possible suggestion for making such a modification comes from Applicants' disclosure, which is impermissible. Only through the teachings of Applicants' own disclosure does one achieve an understanding of how to modify the coloration of the outer coating layer.

Finally, the rejection fails to provide the required expectation of success. Moreover, the person of ordinary skill in the art would perceive just the opposite—an expectation of failure. Modifying Hampton to have different colorations in the coating would render Hampton's tablet unsatisfactory for its intended purpose. As stated above, Hampton describes a tablet having interior colored sections with a clear demarcation line between the sections. Placing a colorant in the coating may prevent a user of the tablet from visualizing the colored sections disposed in the interior of the tablet. As a result, the tablet would be unsatisfactory for its intended purpose because the visualization of the interior colored sections is prevented. Additionally, placing two or more colorants in the coating would result in a coating wherein the colorings are at best only partially mixed together, and at worst completely mixed together so that the resulting coating is a blend of the two colorants. As a result, there would be no clear demarcation line between the first material and the second material and the partially mixing would result in a visual appearance that would vary from one tablet to the next. Such a tablet would be unsatisfactory for its intended purpose, such as branding or tamper indicating, because the tablet would not have a clear demarcation line between the first and second materials. Thus, one of ordinary skill in the art would not be motivated to modify the tablet described in Hampton because such a modification would render Hampton unsatisfactory for its intended purpose.

Appln. No.: 09/842,466  
Reply to Office Action of 07/28/2005

Thus, the claimed invention is patentable over Hampton because Hampton does not disclose or suggest a structure wherein the coating layer has different colorations.

The Office Action further asserts that the Applicants have failed to demonstrate that the claimed invention has any unexpected or surprising results. However, such a demonstration is unnecessary because the Office has failed to establish a *prima facie* case of obviousness.

For each of the above reasons, Claims 31 and 33 are allowable over the cited reference. Further, since Claims 6 – 9, 11, 13 – 17, and 31 – 44 depend either directly or indirectly on Claims 31 or 33, they are also patentable over the cited references for the above stated reasons.

## **II. Dependent Claims 18-20 and 45-47 are patentable over Hampton in view of Hoover**

Claims 18 – 20 and 45 – 47 have been rejected under 35. U.S.C. § 103(a) as being unpatentable over Hampton in combination with U.S. Patent No. 5,464,631 to Hoover et al. The Examiner alleges that Hoover teaches a two-colored medicant dosage form having embossing, letter, logos, symbols, and the like on the surface of the dosage form.

Hoover describes a caplet wherein a caplet core is encapsulated in a gelatin capsule. The caplet and capsule are of two distinct colors so that the resulting caplet has two colors. Hoover further states that “[i]nsertion of the caplet within one-half of a gelatin capsule also allows for the visual perception of embossed or debossed letters, logos, symbols, and that like that may be placed on the surface of the caplet.” See column 4, lines 37-44. (emphasis added).

Similar, to Hampton, Hoover also does not disclose or suggest a solid preparation having a continuous multi-colored coating layer. Thus, Claims 18 – 20 and 45 – 47 are patentable over the combination of Hampton and Hoover because the references fail to disclose or suggest a solid preparation having a continuous multi-colored film coating layer. Moreover, the claimed invention describes a coating wherein the pattern of two or more different colors is part of the continuous coating. In contrast, Hoover describes a caplet wherein the logos and the like are on the surface of the caplet. Thus, Hoover fails to disclose or suggest a solid preparation where “embossed or debossed letters, logos, symbols, and that like” are an actual part of the coating. Accordingly, Claims 18 – 20 and 45 – 47 are patentable over the cited references. Additionally, Claims 18 – 20 and 45 – 47 are dependent either directly or indirectly on Claims 31 and 33 and therefore are patentable over Hampton whether considered individually or in combination with Hoover.

Appln. No.: 09/842,466  
Reply to Office Action of 07/28/2005

**Conclusion**

Based on the above remarks, it is respectfully submitted that all pending claims are patentable over the cited references, whether considered individually or in combination. Withdrawal of the rejection and allowance of all claims as currently presented is respectfully requested.